

Tab 57

NVE Pharmaceuticals, Inc.

15 Whitehall Road
Andover, New Jersey 07861
Tel: 973-786-7868
Fax: 973-786-7860

33 Newton-Sparta Road
Newton, New Jersey 07860
Tel: 973-383-5444
Fax: 973-383-6785

VIA HAND DELIVERY

June 10, 2003

Alan Slobodin, Esq.
Majority Committee Counsel
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Slobodin:

The following is our third (and final) response to the additional follow-up questions that you posed to NVE Pharmaceuticals through Marc S. Ullman, Esq., our outside counsel, on June 3, 2003. As you know, our first and second responses were submitted on June 4th and 6th, respectively. As noted below, some of the exhibits that were referenced in our June 6th submission are enclosed herein, while other exhibits will be forwarded by our outside counsel.

1. Does Bob Occhifinto own any device by which he can receive e-mail? This includes a computer in his office, home, any other residence, desktop, lap top, blackberry or any other device.

Response: No.

2. If no, explain the circumstances of the creation of the e-mail to Bob Occhifinto referenced in NVE's privilege log.

Response: I, Robert Occhifinto, can not receive electronic communications as I do not personally have, use, or even know how to use any such devices. So-called "e-mail" communications that are intended for me, directly or as a copyholder, have been printed and forwarded to me the same as written memoranda.

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3. Identify any consultant used by the company in connection with GMP issues in its manufacturing facility. This includes consultants retained in connection with the most recent FDA inspection of the company.

Response: Laurence H. Burke, Sr.
FDA Regulatory Consulting, Inc.
862 Yorktown Street
Landsdale, PA 19446

Ray Raskin
FDA Regulatory Consulting, Inc.
862 Yorktown Street
Landsdale, PA 19446

Pam Wertalik
Global Regulatory Partners
135B Washington Ave.
Melbourne, FLA 32951

Sid Rubenstein
Metapharm Consultant
15 Berrian Road
New Rochelle, NY 10804

M. J. Ebanietti
35104 Riverside Court
Leesburg, FL 34788

4. Produce any reports or other material rendered to the company by the consultants identified in 3 above.

Response: Attached hereto as Exhibits A-1 and 2 and A-3 through A-6, are copies of the following reports or other materials prepared by FDA Regulatory Consulting, Inc. and Global Regulatory Partners, respectively:

1. NVE Pharmaceuticals Quality Manual.
2. Suggested responses to FDA Form 483.

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3. GMP Presentation.
4. Employment Ad for Quality Assurance Supervisor.
5. Standard Operating Procedure Form.
6. NVE Standard Operating Procedures.

5. There is an October 4, 2002 memo to Mike Williams regarding the cessation of marketing Stacker 4, yet the chart we produced indicates manufacturing ceased in January, 2003, please explain the reason for this delay.

Response: We decided to manufacture this product for distribution to overseas customers, only, and to discontinue distribution in the U. S. due to weak sales.

6. Why was Stacker 4 discontinued?

Response: We determined that this product was introduced too close in time to our Stacker 3 product and we did not market it aggressively. Therefore, sales were poor, resulting in the discontinuance of the product.

7. When did NVE first become aware that "Yellow Jacket" was a street drug term for a barbiturate?

Response: Shortly after the introduction of our Yellow Jacket product, I learned from several older persons at trade shows that the name "yellow jacket" was a slang term used for a barbiturate in the 1960s and early 1970s. Since this slang term and the drug it referred to had not been in use for some 25-30 years and our Yellow Jacket product was the complete opposite of the drug (our Yellow Jacket was an energy product, not a depressant) and did not look at all like the street drug (which I learned came in a completely yellow capsule), I saw no direct correlation between the two products.

8. Has NVE ever obtained ephedra from a source (this includes any related entities) from which it also purchased synthetic ephedrine or pseudoephedrine at the time it was manufacturing OTC drug products? If yes, provide the details.

Response: Dalian North America in New Brunswick, New Jersey and New Chemic, 50 Chestnut Ridge Rd., Montvale, New Jersey supplied all of the above products including ephedra, ephedrine and pseudoephedrine.

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9. Identify precisely what studies NVE relied upon in formulating its products prior to the publication of the RAND report.

Response: Please see my letter dated June 5, 2003 which provides a narrative of the development of our Yellow Swarm and other products.

10. Can NVE provide information concerning its 2002 revenue at this time? If not, explain why.

Response: Our accountants have not yet compiled and/or completed all the documents necessary to file the 2002 income tax returns.

11. Has NVE filed its 2002 tax returns? If not, explain why.

Response: Our accountants have not yet compiled and/or completed all the documents necessary to file the 2002 income tax returns. Our accountants have filed an application for extension of time to file the 2002 tax returns.

12. Has Bob Occhifinto been deposed in any ephedra related litigation? If yes, provide the details and produce the transcript and exhibits for that deposition.

Response: No.

13. Has any NVE employee, agent, or consultant been deposed in any ephedra related litigation? If yes, provide the details and produce the transcript and exhibits for that deposition.

Response: Yes. Edda Kram and Dora Bhett (a former employee) have been deposed. Transcripts of the depositions (and exhibits) of these individuals will be forwarded to you by our outside counsel, Colingo, Williams, Heidelberg, Steinberger & McElhaney, P.A. of Pascagoula, Mississippi, via overnight mail on Tuesday June 10, 2003.

14. Has Bob Occhifinto ever been deposed in any matter? If yes, provide the details and produce the transcript and exhibits for that deposition.

Response: The depositions that we presently recall are in cases entitled *NVE v. OTC*, *MTV v. NVE, Inc.* and *Hendrickson v. NVE, Inc.* We are in the process of

collecting the transcripts, and expect them to be forwarded to you by our counsel, Nicoll & Davis in Paramus, New Jersey and Pashman Stein in Hackensack, New Jersey.

15. Provide copies of all documents that NVE has produced in any ephedra related litigation.

Response: The documents that are responsive to this question will be forwarded by our outside counsel, Colingo, Williams, Heidelberg, Steinberger & McElhaney, P.A. of Pascagoula, Mississippi, for delivery to you on Wednesday, June 11, 2003.

16. Has NVE ever sued or been sued by another supplement company? If yes, provide the details of that litigation.

Response: A copy of an Order to Show Cause and Verified Complaint in a case entitled *Goen Technologies Corporation v. Robert Emilian and NVE Pharmaceuticals*, which was served on NVE on June 5, 2003, is attached hereto as Exhibit B.

17. Provide a full description of Bob Occhifinto's background. Does Bob Occhifinto have a CV? If yes, provide it.

Response: I was born December 4, 1961. I graduated from Lenape Valley Regional High School in June 1980. I began NVE in 1980 as a retail and mail order operation selling over-the-counter diet and energy products. Between 1983 and 1995, I developed and headed three other businesses that enjoyed various levels of success:

- 1983-1985: Undercurrent Imports imported Marine tropical fish worldwide.
- 1985-1995: NVE Construction built commercial properties and developed raw land into parks and agricultural ponds.
- 1987- 1993: Awbrook Mountain Aqua Farms developed technology to grow commercial quantities of food fish indoors.

In 1987 the operations were consolidated in Newton, NJ.

I have attached a copy of my updated resume as Exhibit C.

18. Aside from the DEA related conviction, has Bob ever been convicted or charged with any other crime? If yes, provide the details.

Response: In the early 1990s I was sentenced to community confinement for bringing a controlled dangerous substance (i.e., hash oil) into the U. S. The substance had been given to me by a friend with whom I had gone on vacation with and was returning from Jamaica. My friend had put the hash oil into a liquor bottle and asked me to carry it for him through Customs so that he would not have to pay extra duty charges on what I thought was a bottle of liquor. I did not know the contents of the bottle. My friend confessed to the (actual) possession (i.e., owning) of the hash oil and was later sentenced.

In the early 1990s I was charged with the destruction of the property of someone that repeatedly trespassed and stole from me.

19. What were the company's annual levels of distribution of ephedra related products from 1994 to 1999?

Response: Attached hereto as Exhibit D is a compilation of the annual sales of NVE's ephedra related products from 1996-1999. We were not able to determine the level of sales of ephedra related products before 1996. *why?*

20. What was the basis for the decision to use 10mg more ephedra in the Yellow Swarm formulation? Who made this decision? How was this decision made?

Response: Please see my letter dated June 5, 2003 which provides a narrative of the development of our Yellow Swarm and other products. *non-response*

21. Provide all of Bob Occhifinto's handwritten notes relating to the formulation of any ephedra product.

Response: There are none.

22. Identify all of Bob Occhifinto's assistants from 1994 to the present. Provide their names, and current addresses and telephone numbers.

Response:

1997-1998 Diane Brennan
32 Hamburg Ave.
Sussex, NJ 07461
973-875-4069

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1999-2000 Elaine Schumm
9 Linwood Ave
Newton NJ 07860
973-383-2760

2001-2002 Valerie Evans
21 Tess Drive
Lafayette NJ 07848
973-579-4860

2002-present Dianna Torre
905 Pepperidge Drive
Newton, NJ 07860
973-948-2318

23. Identify all outside labs utilized in connection with any testing relating to any ephedra product. Describe the nature of the testing.

Response: Lycoming Labs, Duboistown, PA; and Boston Analytical, Salem NH
Raw materials are tested to determine the level of ephedrine alkaloids.

24. Is there a memo to Mike Williams concerning the cessation of the production of Yellow Jackets? If yes, provide that document. If no, describe the manner in which the factory and warehouse were advised to cease shipping and manufacturing.

Response: Yes. Attached hereto as Exhibit E is a copy of the memo dated October 16, 2002.

25. Describe NVE's relationship with NASCAR. Include information concerning the sponsorship of races and of a racecar.

Response: Attached hereto as Exhibit F is a copy of the contract between NVE Pharmaceuticals and Bill Davis Racing, Inc., dated August 20, 2002, that is responsive to this question.

26. Provide copies of all correspondence with outside counsel in any ephedra related case, or provide a privilege log of such communications.

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Response: Attached hereto as Exhibit G is an attorney-client/work-product privilege log of the communications that are responsive to this question.

27. Provide all company manuals – organizational charts, job responsibilities, SOPs.

Response: See Exhibit A. Also, attached hereto as Exhibits H-1 & H-2 are copies of the following documents:

1. Employee Manual
2. Organizational Chart

Very truly yours,



Robert Occhifinto,
President

C: David C. Caldwell, General Counsel, NVE Pharmaceuticals
Marc S. Ullman, Esq., Ullman Shapiro, Ullman
James H. Colmer, Jr., Esq. Colingo, Williams, Heidelberg Steinberger & McElhaney (w/o enc.)
Anthony J. Davis, Esq., Nicoll & Davis (w/o enc.)
Samuel J. Samaro, Esq., Pashman Stein (w/o enc.)